



STATISTICS & PROGRAMMING

OUR EXPERTISE

1. DATA MANAGEMENT SUPPORT

- SDTM
- Data integration & standardization
- Patient data listing
- Medical review listing
- Patient profiles

2. PROGRAMMING

- ADAM
- TLGs
- SAS programming
- SAS macro generation
- R programming
- R package generation
- Python

3. STATISTICS

- Study design & consulting
- Power analysis & sample size calculation
- Adaptive designs
- Bayesian designs
- Randomization
- Statistical analysis plans
- Statistical analysis
- Meta-analyses
- Clinical study report review
- Unblinded interim analysis (DSMB)
- Regulatory agency discussions

OUR WORKFLOW



CONSULTING

- Sample size
- Synopsis / Protocol Statistical part
- Statistical Methodology



ANALYSIS PLAN

- Statistical Analysis Plan
- ADaM and TLF specifications



STATISTICAL ANALYSIS

- Interim analysis
- Final analysis
- ADaM and TLF programming



REPORTING

- Statistical Report
- Final TLF production



PRESENTATION

- Statistical input into
- Manuscript
- Poster
- Slides

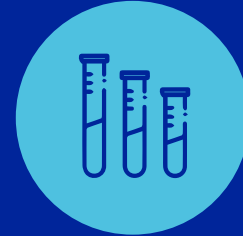
TEAM OF EXPERTS

30+ Years Biostatistics Expertise



46 MEMBER TEAM

33 Statisticians & Stat Programmers
13 Stat Programmer



13 YEARS EXPERIENCE IN AVERAGE

High level of task-related expertise,
with up to >30 years of experience



STATISTICIANS: MASTER+ PROGRAMMERS: BACHELOR+

Our Statisticians have a Master/PhD
in Statistics or Mathematics
Programmers have a Bachelor in
a programming related field

MULTIPLE THERAPEUTIC AREAS AND PHASES

Experience with clinical studies
across therapeutic areas and
phases:

- Phase I to IV, late phase
- Oncology, Infectious disease,
CNS, Hormonal Disease, Meta-
bolic Disease, Nutrition...

CASE STUDY: PROGRAMMING OF SDTM



CHALLENGE

20 clinical trials were performed in >20 countries
on one common protocol with local (Country)
adaptations over 4 years.

SOLUTION OFFERED

Same edc platform was used for all trials and
the programming was performed in modules
for each domain with global macro parameters.

BUSINESS IMPACT

Global protocol adaptations could be incorporated
within very short amount of time.
Local adaptations were handled easily and flexible.

For further information, please email : contact@excelya.com